UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

ORTHO-MCNEIL PHARMACEUTICAL, INC.,

Plaintiff,

Case No. 04-CV-73698

vs.

HON. GEORGE CARAM STEEH

CARACO PHARMACEUTICAL LABORATORIES, LTD.,

Defendant.
_____/

ORDER DENYING PLAINTIFF'S MOTION TO TRANSFER (DOCUMENT # 9)

This case arises out of a patent infringement action brought by plaintiff Ortho-McNeil Pharmaceutical Inc. ("Ortho-McNeil") against defendant Caraco Pharmaceutical Laboratories Ltd. ("Caraco"), a company seeking to manufacture a generic version of Ortho-McNeil's Ultracet drug product. Plaintiff filed the lawsuit in this court, and now seeks to transfer to the United States District Court for the District of New Jersey, where two similar cases are pending against two other generic drug manufacturers involving the same patent and generic copies of the same drug that Caraco is seeking to market. For the reasons given below, plaintiff's motion to transfer pursuant to 28 U.S.C. § 1404(a) is DENIED.

FACTUAL BACKGROUND

Plaintiff sells the FDA-approved New Drug Application ("NDA") No. 21-123 for the short term management of acute pain, using the tradename Ultracet. Ultracet is an

extremely successful product, with sales in the United States in excess of 300 million dollars per year.

Defendant Caraco is a Michigan corporation engaged in the business of developing, manufacturing, and marketing generic drugs. It does not maintain any offices, lease any property, or have any facilities in New Jersey. The distribution of its products is handled through independent distributors - two to four of which are headquartered in New Jersey.

Caraco is the third generic drug manufacturer to file an Abbreviated New Drug Application ("ANDA") seeking permission to market a generic copy of the patent-protected Ultracet. The first two ANDAs were filed by Kali Laboratories, Inc. ("Kali") and Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc. ("Teva"). Plaintiff brought suit against Kali and Teva pursuant to the Hatch-Waxman Act, alleging infringement of the '691 patent.

Plaintiff filed suit against Kali in November 2002, and against Teva in January 2004. Both suits were filed in New Jersey, where Kali, Teva, plaintiff, and a sizable portion of the pharmaceutical industry are located. The cases were assigned to different judges, and a request by plaintiff to have them consolidated or reassigned was denied because the cases were on different timelines. Teva chose to forego its own discovery and rely on the Kali material, so the schedules of the two cases have since converged. Discovery closed in the Kali case, and was scheduled to close on May 20, 2005 in the Teva case. Substantially identical summary judgment motions have been filed, addressing the issues of infringement and validity. Plaintiff has filed another motion to consolidate the cases, that is fully briefed and awaiting decision.

Caraco sent plaintiff notification of its ANDA in August 2004 and plaintiff filed suit in September 2004. Plaintiff requested that Caraco consent to jurisdiction in New Jersey, but Caraco declined. Plaintiff brought this action in Detroit, where Caraco is based. Plaintiff explains that it took a cautious view of personal jurisdiction due to the intricacies of the Hatch-Waxman Act.

The Hatch-Waxman Act requires the FDA to stay approval of ANDAs for 30 months while the ANDA filer and NDA/patent holder litigate the patent issues. 21 U.S.C. § 355(c)(3). The 30-month stay is only enforced if "an action is brought for infringement" by the NDA/patent holder within 45 days of receiving the generic drug manufacturer's notification of its ANDA, and if the NDA/patent holder does not receive an adverse ruling. Plaintiff was fearful that if it brought suit against Caraco in a jurisdiction where the court later determined personal jurisdiction was lacking and dismissed the case, it could potentially lose the benefit of the 30-month stay.

After filing this case, plaintiff approached defendant about transferring the case to New Jersey. Defendant instead suggested the case be stayed pending the outcome of the New Jersey cases, and that the parties agree to accept certain outcomes of the New Jersey cases as binding in this case (validity and enforceability, but not infringement or claim construction). The parties delayed discovery while they tried to work out an agreement, but have recently reached an impasse. There is a discovery schedule in place, and on March 11 plaintiff served all the documents produced by it in the Kali and Teva cases, as well as the pleadings and discovery requests and responses, transcripts, exhibits and videotapes of Ortho-McNeil fact witness depositions in those cases. Defendant is reviewing the material to determine if it needs to take

more fact discovery. Plaintiff states that it is willing to narrow the scope of fact discovery on its part. As for expert discovery, plaintiff will rely on the validity and enforceability expert reports from the Kali and Teva cases.

There are two issues in this case: (1) whether Caraco's generic copy of Ultracet infringes the '691 patent and (2) whether the '691 patent is valid and enforceable. Plaintiff maintains that most of the fact witnesses on these issues are located in or around northern New Jersey. Plaintiff argues that testimony from Caraco's employees should be unnecessary because any testimony regarding the issue of infringement will be limited to expert testimony because the alleged infringing products are hypothetical and defined solely by reference to Caraco's ANDA. As for validity and enforceability of the '691 patent, plaintiff contends that nearly all likely fact witnesses are current or former Ortho-McNeil/Johnson & Johnson employees living in or around northern New Jersey. Plaintiff lists third parties who were deposed by Kali and may be third party witnesses at a trial in this case: the inventors of the '691 patent reside in Philadelphia, the statistician who did analysis of the animal test data in the '691 patent resides in New Jersey, the lab assistant who assisted in preparation of the animal test data resides in Pennsylvania, the clinical investigators who ran early clinical trials reside in New Jersey and New York, and a former employee who oversaw early clinical trials resides in Philadelphia. All of these third parties are within the subpoena power of the New Jersey court.

Plaintiff makes an argument that defendant should be registered as a drug manufacturer or wholesale drug distributor in New Jersey, under New Jersey law. N.J. Admin. Code § 8:31-3A.4. Plaintiff also argues that defendant has fifteen products

listed on the New Jersey Generic Formulary. Plaintiff argues that the submission of applications for these products constitutes substantial contact with the state of New Jersey.

ANALYSIS

I. Transfer of Forum by Plaintiff

The change of forum statute provides that "[f]or the convenience of parties and witnesses, in the interest of justice, a district court may transfer any civil action to any other district or division where it might have been brought." 28 U.S.C. § 1404(a). The Sixth Circuit has recognized that there are instances where it may be appropriate to grant a motion to transfer brought by a plaintiff:

> The right to a transfer under the statute is available to a plaintiff as well as a defendant. A plaintiff is not bound by his choice of forums, if he later discovers that there are good reasons for transfer. A judge in his discretion may take this into consideration in determining if a transfer should be granted.

Philip Carey Mfg. Co. v. Taylor, 286 F.2d 782, 784 (6th Cir. 1961). In all of the cases brought to the attention of the court, it was considered to be significant that the plaintiff discovered good reasons for a transfer *after* the initial choice of forum. In Philip Carey the Court did state that the demonstration of post-filing events is *one* factor a court may consider when exercising its discretion to transfer a case. Therefore, there is not an immutable rule prohibiting courts from considering factors known at the time suit was filed.

Plaintiff in this case first concedes that since it filed the complaint, there have been no changed circumstances that justify transfer. Instead, plaintiff explains that it chose not to file suit in New Jersey in the first instance because the New Jersey court

might have found that it did not have personal jurisdiction over defendant. Plaintiff was allegedly fearful that if its lawsuit was dismissed for lack of personal jurisdiction, the 30-month stay of defendant's ANDA application provided by the Hatch-Waxman Act might not be enforced. Plaintiff made the tactical decision to pursue its lawsuit in this forum, and try to transfer venue after the lawsuit was filed. Defendant characterizes plaintiff's tactics in the following way: "Ortho has brought the action here in order to try to litigate the issue of personal jurisdiction via a transfer motion, without the risk of having its case dismissed." Defendant warns that the transfer statute does not permit a plaintiff to engage in this sort of manipulation of forums, otherwise a motion to transfer venue could enable the plaintiff to shop for a particular forum or judge.

The plain language of section 1404(a) provides for transfer for the convenience of the parties and witnesses, and in the interest of justice. There is no requirement that the request come from any particular party or that reasons for transfer arise after the complaint is filed. However, it seems unlikely that the drafters intended to permit plaintiffs to bring a motion for forum nonconveniens without some very good reason. The presumption against changing a plaintiff's choice of forum still applies when the plaintiff makes the motion to transfer.

Plaintiff argues that defendant's unilateral withdrawal of its stay offer and evidence made available to plaintiff only recently by way of the Jitendra Doshi deposition, represent "changed circumstances" justifying transfer. However, it does not appear to the court there was a stay offer by defendant. At most there was an offer to discuss a stay. Therefore, the court will consider the information revealed in the Doshi deposition in deciding the pending motion.

II. Forum Nonconveniens Analysis

Under 1404(a), to justify transferring a case, the movant must demonstrate that: (1) the action could have been brought in the transferee court; (2) transfer is for the convenience of the witnesses and parties; and (3) transfer serves the interest of justice. McCuiston v. Hoffa, 313 F. Supp. 2d 710, 719 (E.D. Mich. 2004). In order to establish whether the forum is sufficiently convenient and in the interest of justice, courts consider (1) the relative ease of access to sources of proof; (2) the availability of process to compel attendance of unwilling witnesses; (3) the cost of obtaining willing witnesses; and (4) the practical problem associated with trying the case most expeditiously and inexpensively. Id.

A. Action Could have Been Filed In New Jersey

The United States District Court for the District of New Jersey has subject matter jurisdiction over this case because federal courts have original jurisdiction and exclusive jurisdiction over patent infringement actions.

A federal court sitting in New Jersey has jurisdiction over parties to the extent provided under New Jersey state law. Fed. R. Civ. P. 4(e). New Jersey's long-arm statute provides for jurisdiction coextensive with the due process requirements of the U.S. Constitution. N.J. Court Rule 4:4-4c. Parties who have constitutionally sufficient "minimum contacts" with New Jersey, and where asserting jurisdiction over the party would not offend "traditional notions of fair play and substantial justice", are subject to suit there. Helicoperos Nacionales de Colombia, S.A. v. Hall, 466 U.S. 408, 414 (1984).

Plaintiff alleges that defendant's contacts with New Jersey are sufficiently "continuous and systematic" to justify the assertion of general personal jurisdiction based on its contacts with at least one New Jersey administrative agency and the sales of its other generic drug products in New Jersey. New Jersey has implemented a system governing the automatic substitution of generic versions of branded prescription drugs. The system is run by the New Jersey Drug Utilization Review Council and requires pharmacists to substitute generic drugs for their brand name counterparts even if the doctor's prescription does not specifically allow such substitution. To be eligible for this automatic substitution, a generic drug must be on the New Jersey Generic Formulary. Plaintiff alleges that defendant has gone through an application process for at least fifteen generic drugs in order to be listed on the Formulary. Plaintiff argues that this qualifies as continuous and systematic contacts with New Jersey. In addition, it demonstrates defendant's goal of selling its drug products in New Jersey.

Defendant disputes that its inclusion on the New Jersey Formulary is evidence that it solicits substantial or continuous business with New Jersey. Mr. Doshi, chief executive officer of defendant, testified that defendant has not had any contacts with the New Jersey Formulary in the last 1 ½ to 2 years. Furthermore, Mr. Doshi explains that in the last couple of years generic drugs are automatically listed on the New Jersey Formulary after approval by the U.S. Food and Drug Administration. Therefore, defendants applications were two years old at the time plaintiff's lawsuit was filed.

Defendant's additional uncontested contacts with New Jersey can be summed up as follows. Defendant contracts with two to four independent distributors and one PBM (Pharmacy Benefit Manager) which are headquartered in New Jersey. The drugs are

actually shipped by defendant to any place in the country that the distributors request they be shipped. Defendant does not advertise in New Jersey, and is not licensed to do business in the state. Defendant did employ a sales representative in New Jersey, but he was terminated two years ago, and was not replaced. Defendant made telephone calls and had email communications with its three to five New Jersey customers, as well as occasional face-to-face visits.

In Michigan Nat'l Bank v. Quality Dinette, Inc., 888 F.2d 462 (6th Cir. 1989), the Sixth Circuit found "continuous and systematic" contacts where, in the year preceding the action, the plaintiff had dozens of sales in Michigan, retained an independent sales representative in the state, and conducted mail order solicitations of Michigan customers. Furthermore, plaintiff made at least one sale in Michigan each month during the two years prior to suit being filed. These figures represent only 3% of plaintiff's total sales during those years, but when viewed with all other relevant factors, the evidence was found to be sufficiently "continuous and systematic."

In Conti v. Pneumatic Products Corp., 977 F.2d 978 (6th Cir. 1992), defendant sold its products in Ohio through two distributors. The distributors acted as defendant's agents in connection with defendant's direct sales to end users, and they regularly purchased defendant's products for resale in Ohio. Defendant's employees occasionally visited and telephoned the distributors with technical support, but the distributors mostly served the products they sold. The court held plaintiff did not establish a prima facie case that defendant's contacts were of a "continuous and systematic" nature to maintain general jurisdiction over defendant in Ohio. Id. at 981.

In the present case, defendant contracts with at least two independent distributors and one PBM in New Jersey. Mr. Doshi explained that someone from defendant's marketing department goes to New Jersey to meet with the distributors three to four times a year. The purpose of the visits is to make the distributor aware of all of defendant's products and to see if they are interested in selling defendant's other products. Defendant had net sales in New Jersey of $2.5 million in the previous two years, which translates to 4-5% of its U.S. sales. Three to four visits to the state a year, and 4-5 % of sales do not rise to the level of "continuous and systematic."

B. Convenience of Witnesses and Parties

Plaintiff argues that many third parties live closer to New Jersey than Detroit, and that this court lacks subppoena power over most witnesses. While Philadelphia is indeed closer to New Jersey than Detroit, it is not substantially more burdensome to fly between Philadelphia and Detroit than it is to fly between Philadelphia and New Jersey. Furthermore, whether an individual is subject to the subpoena power of the court only becomes a factor when the individual is unwilling to attend trial in the forum. Plaintiff has not shown that any of its witnesses are unwilling to testify in Detroit.

C. Interest of Justice

The movant bears the burden of demonstrating that "fairness and practicality strongly favor the forum to which transfer is sought." The movant must make this showing by a preponderance of the evidence. Audi AG and Volkswagen of America v. D'Amato, 341 F. Supp. 2d 734, 749 (E.D. Mich. 2004) (citations omitted). Here, transfer to New Jersey will merely shift the burdens of this litigation from plaintiff to defendant.

Plaintiff argues that transfer should still occur because (1) the Kali and Teva cases are already pending in New Jersey, and (2) the witnesses are located closer to New Jersey.

The Kali and Teva cases have not been consolidated, are on the dockets of two different judges, and are much older than this case. The court does not agree that this factor favors transfer.

CONCLUSION

In balancing the relevant factors known to the court at this time, the court concludes that plaintiff's original choice of forum should prevail. Plaintiff's motion to transfer is DENIED.

s/George Caram Steeh
GEORGE CARAM STEEH
UNITED STATES DISTRICT JUDGE

Dated: June 14, 2005

CERTIFICATE OF SERVICE

Copies of this Order were served on the attorneys of record on June 14, 2005, by electronic and/or ordinary mail.

s/Josephine Chaffee
Secretary/Deputy Clerk